

REMARKS

The present application includes pending claims 1-20, all of which were rejected. By this Amendment, claims 1 and 7 have been amended as set forth above. The Applicant respectfully requests reconsideration of the claim rejections.

Claims 1-6 stand rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent No. 4,722,348 (“Ligtenberg”). Claims 7-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ligtenberg in view of United States Patent No. 5,803,089 (“Ferre”). The Applicant respectfully traverses these rejections for at least reasons previously discussed during prosecution and the following:

I. Ligtenberg Does Not Anticipate Claims 1-6

The Applicant first turns to the rejection of claims 1-6 as being anticipated by Ligtenberg. “A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in **a single prior art reference.**” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). “The **identical** invention must be shown in as complete detail as is contained in ... the claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added).

A. Ligtenberg Does Not Describe, Teach Or Suggest Providing Information Regarding A Location Of An Operative Tip Of A Device

Claim 1 has been amended to recite “wherein said strain gauge **detects deflection** of said flexible engaging member, wherein the detection of deflection of said flexible engaging member **provides information regarding a location of said operative tip.**”

On the other hand, Ligtenbeg discloses a “catheter tip pressure transducer [that] is employed for purposes of **measuring fluid pressure within a living body.**” Ligtenberg at Abstract (emphasis added). Ligtenberg “relates to the art of **pressure sensors** and, more particularly, to a catheter tip pressure transducer of sufficiently small size that may be employed **for measuring fluid pressure, such as blood pressure,** within the human body.” *Id.* at column 1, lines 5-9 (emphasis added). In particular, “[p]ressure forces acting on the membrane beam result mainly in longitudinally extending deformation of the beam and this is sensed by one or more strain gauges carried by the beam.” *Id.* at Abstract. Thus, Ligtenberg discloses a system in which strain gauges are used **to sense membrane deformation resulting from fluid pressure** on the membrane. *See id.*, e.g., at column 3, lines 18-25 (“This **pressure responsive membrane** deforms in dependence upon the **pressure** being monitored. This deformation is sensed by strain gauges in the form of piezoelectric resistors carried by the membrane....”).

As shown in Figure 2 of Ligtenberg, the membrane 38 is located **within** the tubular housing 14 of the catheter proximate an inlet 16. *See id.* at Figure 2.

The membrane 38 faces the inlet aperture 16 so that pressure variations in a blood vessel or the like may be communicated to the membrane. The membrane is responsive to the pressure and flexes or deforms as a result thereof.

Id. at column 3, lines 64-68. The deformation caused by pressure variations is sensed by resistors on the membrane. *See id.* at column 5, lines 22-26. Thus, the strain gauges disclosed in Ligtenberg are positioned on a deformable membrane that is responsive to fluid pressure variations. The strain gauges are used to detect the deformation of the membrane and, therefore, **the level of fluid pressure**, but not location of the catheter. That is, the strain gauges disclosed

in Ligtenberg are not positioned on any portion of the catheter that would allow the strain gauges to measure deflection of the catheter tip.

Ligtenberg does not describe, teach or suggest, however, “wherein said strain gauge **detects deflection** of said flexible engaging member, wherein the detection of deflection of said flexible engaging member **provides information regarding a location of said operative tip**,” as recited in claim 1, as amended. Again, the strain gauges of Ligtenberg are positioned on a deformable membrane **within** a catheter and are **used to sense the amount of fluid pressure** (such as a patient’s blood pressure) **on the membrane, but are not positioned on any portion of the catheter itself that would allow them to detect deflection of the catheter tip**. Thus, for at least these reasons, the Applicant respectfully submits that Ligtenberg does not anticipate claims 1-6.

B. Response To Perceived Assertion Of Official Notice

The current Office Action responds to the Applicant by stating the following:

[O]ne could certainly argue that by sensing the external pressure with the reference transducer, one can infer information regarding the location of the device. For instance, it is known in the art that the pressure of flowing blood varies predictably within the cardiovascular anatomy, and therefore the sensed pressure can indeed provide information regarding the catheter’s location within the patient.

*See November 23, 2007 Office Action at page 2. Initially, none of these summary conclusions in the current Office Action are disclosed in Ligtenberg. As noted above, in order to establish a *prima facie* case of anticipation, the “**identical** invention must be shown in as complete detail as is contained in ... the claim.” Richardson, 868 F.2d at 1236, 9 USPQ2d at 1920 (emphasis*

added). Thus, for at least this reason, the Office Action has not established a *prima facie* case of anticipation with respect to claims 1-6.

Next, the Applicant respectfully submits that one cannot **reasonably** argue that a location of a catheter can be determined through fluid pressure sensing, merely through the disclosure of Ligtenberg. Indeed, the Office Action has not provided any factual evidence for the summary conclusions noted above (e.g., that blood pressure detection provides information of a catheter tip position).

Moreover, the statements from the current Office Action reproduced above, because of the manner in which they are worded, could be interpreted as assertions of Official Notice of the subject of the statements. If the Examiner is asserting Official Notice that the subject of the statements are common knowledge, the Applicant respectfully traverses the Examiner's assertions as further set forth below. Alternatively, if the Examiner's assertions are based on the personal knowledge of the Examiner, then under MPEP § 2144.03(C) and 37 C.F.R. § 1.104(d)(2), the Examiner's assertions must be supported by an affidavit from the Examiner.

According to MPEP § 2144.03(A), Official Notice, without supporting references, should **only** be asserted when the subjects asserted to be common knowledge are “capable of instant and unquestionable demonstration as being well-known.” That is, the subjects asserted must be of “notorious character” under MPEP § 2144.03(A).

However, the Applicant respectfully submits that the subject matter of the perceived assertions of Official Notice are not well-known in the art as evidenced by the searched and cited prior art. The Applicant respectfully submits that the Examiner has performed “a thorough

search of the prior art,” as part of the Examiner’s obligation in examining the present application under MPEP § 904.02.

Additionally, the Applicant respectfully submits that the Examiner’s searched and cited references found during that thorough and detailed search of the prior art are indicative of the knowledge commonly held in the art. However, in the Examiner’s thorough and detailed search of the relevant prior art, none of the prior art taught or suggested the subject matter of the perceived assertions of Official Notice. That is, the Examiner’s thorough and detailed search of the prior art has failed to yield any mention of the teachings that the Examiner is asserting as widely known in the art (e.g., “that the pressure of flowing blood varies predictably within the cardiovascular anatomy, and therefore the sensed pressure can indeed provide information regarding the catheter’s location within the patient”). The Applicant respectfully submits that if the subject matter of the perceived assertion of Official Notice had been of “notorious character” and “capable of instant and unquestionable demonstration as being well-known” under MPEP § 2144.03(A), then the subject matter would have appeared to the Examiner during the thorough and detailed search of the prior art.

If the Examiner had found any teaching of relevant subject matter, the Examiner would have been obligated to list the references teaching the relevant subject matter and make a rejection. Consequently, the Applicant respectfully submits that the prior art does not teach the subject matter of the perceived assertions of Official Notice and respectfully traverses the perceived assertions of Official Notice.

The Applicant specifically challenges the perceived assertions of Official Notice with regard to the following:

1. “[O]ne could certainly argue that by sensing the external pressure with the reference transducer, one can infer information regarding the location of the device,” and
2. “[I]t is known in the art that the pressure of flowing blood varies predictably within the cardiovascular system, and therefore the sensed pressure can indeed provide information regarding the catheter’s location within the patient.”

As stated above, the Applicant respectfully traverses the perceived assertions of Official Notice and submits that the subject matter is not of such “notorious character” that it is “capable of instant and unquestionable demonstration as being well-known.” Under MPEP 2144.03, the Examiner is now obligated to provide a reference(s) in support of the perceived assertions of Official Notice if the Examiner intends to maintain any rejection based on the perceived assertions of Official Notice. Additionally, the Applicant respectfully requests the Examiner reconsider the perceived assertions of Official Notice and provide to Applicant any basis for the perceived assertions.

C. Ligtenberg Does Not Describe, Teach Or Suggest Strain Gauges Affixed To A Catheter

Claim 4 recites, in part, “a strain gauge affixed to a portion of said flexible engaging member, . . . wherein said flexible engaging member is one of a needle, catheter, curette, and K wire.” Ligtenberg discloses that strain gauges are positioned on a deformable membrane 38 located within a catheter. Ligtenberg does not describe, teach or suggest, however, that strain gauges are affixed to the catheter itself. Thus, for at least this reason, the Applicants respectfully submit that Ligtenberg does not anticipate claim 4.

II. The Proposed Combination Of Ligtenberg And Ferre Does Not Render Claims 7-20 Unpatentable

The Applicant next turns to the rejection of claims 7-20 as being unpatentable over Ligtenberg in view of Ferre. Claim 7 recites, in part, a “deflection tracking system comprising at least one strain gauge affixed to a portion of said flexible engaging member, said at least one strain gauge providing information regarding a location of said deflectable operative end,” as amended. The Applicant respectfully submits that neither Ligtenberg, nor Ferre, describe, teach or suggest this limitation, for at least the reasons discussed above in Sections I.A and I.B. Thus, the proposed combination does not render claims 7-13 unpatentable.

The Applicant also notes that the proposed combination does not render claim 12 unpatentable for at least the reasons discussed above with respect to claim 4.

Claim 14 recites, in part, “using a second tracking method to track deflections of an operative tip of the medical instrument.” As discussed above, Ligtenberg discloses attaching strain gauges to a deformable membrane within a catheter to determine fluid pressure variations. Neither Ligtenberg, nor Ferre, describe, teach or suggest “using a second tracking method to track deflections of an operative tip of the medical instrument.” Thus, the proposed combination does not render claims 14-20 unpatentable.

III. Conclusion

In general, the Office Action makes various statements regarding the pending claims and the cited references that are now moot in light of the above. Thus, the Applicant will not address such statements at the present time. The Applicant expressly reserves the right, however, to challenge such statements in the future should the need arise (e.g., if such statement should become relevant by appearing in a rejection of any current or future claim).

If the Examiner has any questions or the Applicant can be of any assistance, the Examiner is invited to contact the undersigned attorney. While no fee is believed due with respect to this Amendment, the Commissioner is nonetheless authorized to charge any necessary fees, or credit any overpayment to Deposit Account 50-2401.

Respectfully submitted,

Date: December 6, 2007

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